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Ruchika Singhal

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

06/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiplaw.com

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-10, 12-15, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 1 and 9, the Examiner was unable to find support in the originally-filed disclosure for an overmold that integrates modules into a desired form factor, but, where flexible, allows relative intermodule motion. Although the Examiner was able to find support for various structures to prevent intermodule motion, this is not a disclosure that the modules have relative motion, or that this intermodule motion is provided by virtue of the overmold. Regarding claim 19, the Examiner was unable to find support in the originally-filed disclosure for a housing of the control module that is hermetic. Although the original disclosure indicates that hermetic IMD housings are known in the prior art, the Examiner was unable to locate support for a hermetic control module.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-5, 8-10, 12-13, 15, and 19-21 are rejected under 35 U.S.C. 102(a/e) as being unpatentable over Berrang et al. (US 6,358,281, hereinafter “Berrang”), or in the alternative, under 103(a) over Berrang in view of Correas (US 6,112,120, hereinafter “Correas”).

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7. In regards to claims 1 and 9, Berrang discloses an implantable device comprising at least two interconnected modules (Fig. 2, elements 18 and 21, and the material directly surrounding elements 18 and 21, such as 24, 20, 25, and 23), each having a housing (24, 20, 25, and 23); and an overmold encapsulating each of the housings (col. 9, lines 51-62 and col. 11, line 55-col. 12, line 25; element 6; and the disclosed gold and titanium, platinum, silicone, and/or any combination of these) comprising a first material and a second material (the disclosed gold and titanium, platinum, silicone, and/or any combination of these; col. 9, lines 51-62; and element 6) one of which is at least partially flexible to allow relative motion between the modules (element 6 and col. 9, lines 51-62) and comprising a lead connection module (Fig. 1, element 6) configured to accept an external lead (16), the module (6) being embedded within the overmold (because it too is coated with the gold and silicone disclosed at col. 9, lines 51-62), and the module (6) inherently comprises at least one feed-through wire that connects the lead (16) to the power source and control electronics housed within the other two modules (depicted in element 6 in Fig. 2, but lacking a reference numeral). Please note an alternate interpretation wherein electronic module (21) is housed by support disc (33) and battery (18) inherently comprises its own housing because the battery is a lithium ion or nickel metal hydride-type (col. 12, line 55). These batteries contain liquid electrolytes, necessitating a housing. Berrang does not expressly disclose that the lead (16) is “separable from the lead connection module.” However, the lead is constructed of platinum and an inert polymer (col. 11, lines 3-27), which is inherently “separable from the lead connection module” by use of, e.g., wire cutters. In the alternative, Correias

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teaches a cochlear implant system (col. 1, line 16) having a lead that is manually separable and re-attachable to a lead connection module to provide the predictable result of allowing convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection (col. 1, lines 58-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention by providing a lead that is manually separable and re-attachable to a lead connection module to provide the predictable result of allowing convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection.

8. In regards to claim 2, at least one module contains electronic components (21).

9. In regards to claims 3 and 13, the overmold comprises a first material and a second material (col. 9, lines 51-62 and col. 12, line 8) and the lead connection module is embedded within the first material (because the lead conductors must pass through all coating materials (the epoxy, gold, palladium, titanium, and silicone of col. 9, lines 51-62 and col. 12, line 20) to reach the outside of the device, the lead connection module is "embedded in" the "first material"). This connection module comprises the conductors that connect 16 with the internal electronics 21.

10. In regards to claims 4 and 10, the first material is non-elastomeric (gold).

11. In regards to claim 5, the device includes at least one feed-through wire (col. 11, line 3).

12. In regards to claim 8, the maximum thickness is between 4 and 8 millimeters (col. 10, line 9).

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- 13.** In regards to claim 12, the second material is silicone (col. 12, line 25).
- 14.** In regards to claim 15, the modules are horizontally distributed and separately encapsulated by the overmold (Fig. 2).
- 15.** In regards to claims 19 and 20, the at least one of the modules/the control module is hermetic via the overmold (col. 12, line 18; with respect to the outside of the device). In the alternative, Berrang discloses the claimed invention but does not disclose expressly the hermetic control electronics housing. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the control module encapsulation as taught by Berrang with the individual hermetic seal because applicant has not disclosed that individual hermetic seals provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the implant as taught by Berrang because both systems hermetically seal the components from the body (col. 11, lines 55-67). Therefore, it would have been an obvious matter of design choice to modify Berrang's invention to obtain the invention as specified in the claims.
- 16.** In regards to claim 21, the overmold partially encapsulates each of the housings (in this case, the "overmold" is considered to be the epoxy (col. 11, lines 60-66) and the bridge 6, i.e., does not include the gold and/or silicone coating).

Claims 6, 7, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang in view of Correas. Berrang discloses the essential features of the claimed invention except for an isodiametric lead or tool-less mechanical connection. Correas

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teaches providing implantable devices with isodiametric lead connection modules (Fig. 1) to allow the use of conventional leads and to provide tool-less lead securing (Figs. 5 and 6) to provide the predictable result of a simple implantation that requires few implantation implements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention by providing an isodiametric lead connection module to allow the use of conventional leads and to provide tool-less lead securing to provide the predictable result of a simple implantation that requires few implantation implements.

Response to Arguments

17. Applicant's arguments filed 5/29/2009 have been fully considered but they are not persuasive. In regards to the objection to the specification and new matter rejection under 112(1), the amendments to the specification comprise "essential material" because they are required to provide written description of the invention. As "essential material," the incorporation by reference must be to a patent or patent application publication. See 37 C.F.R. 1.57(c). The instant specification objection and new matter rejections will be obviated, and the previous specification amendments entered upon amendment of paragraph 0002 of Applicant's disclosure to include reference to the patent application *publications* instead of merely the application numbers.

18. In regards to the art rejections of claims 1 and 9 under 102(a/e) and/or 103(a), applicant argued that the rationale to combine provided by the Examiner lacks rational underpinning. It is noted that Applicant did not address the rejection under 102(a/e) wherein the Examiner takes the position that the lead is separable by scissors or wire

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cutters, as set forth above. Applicant's position appears to be that avoiding a "risk of inopportune disconnection" is not a rational basis for combining Berrang and Correas because Berrang's device does not allow for a "risk of inopportune disconnection," and thus an artisan of ordinary skill would not be motivated to look to Correas to cure a deficiency that does not exist. However, the basis is not merely to avoid inopportune disconnection, but to allow convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection. In other words, this modification allows a surgeon to implant a lead, and then immobilize it on the generator without risk of later disconnection from either the generator or the implantation site, as is notorious in the electrical stimulator arts. Further, there is no requirement under 103(a), or the interpretive *KSR* decision, that requires a motivation of an artisan of ordinary skill to recognize a shortcoming in Berrang and look to outside teachings, like Correas, to cure said shortcoming. Combining known elements (like pulse generators and connectors) by known methods to produce predictable results is a sufficient "rational underpinning." See MPEP 2141(I).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
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